



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,215	06/24/2003	Neema M. Kulkarni	PC 21501B	2258
28880	7590	09/13/2004	EXAMINER	
WARNER-LAMBERT COMPANY 2800 PLYMOUTH RD ANN ARBOR, MI 48105			COOK, REBECCA	
			ART UNIT	PAPER NUMBER
			1614	
DATE MAILED: 09/13/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/602,215

Applicant(s)

KULKARNI ET AL.

Examiner

Rebecca Cook

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/30/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 15 is objected to under 37 CFR 1.75 as being a substantial duplicate of claims 1 and 13. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

It is inherent that the compositions of claims 1 and 13 have the usage recited in claim 15. If the intent is to recite a method of using the composition, then the claim should be amended to recite a method of use.

Claim Rejections - 35 USC § 112

Claims 1-5 and 12-13 and 15, to the extent that they depend from claim 1, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 does not recite a GABA analog in the body of the claim. Furthermore, the first time that an abbreviation appears in a claim is should be in parentheses and be preceded by the term for which it is an abbreviation.

There is no antecedent basis in claim 1 for the ingredients of claim 5.

In claim 14 the phrase "characterized by" is colloquial and is not clear.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/59573.

WO 99/59573 (page 50, lines 7-21, pages 58-61, Examples 2 and 3) discloses a liquid composition of a GABA analog comprising a polyhydric alcohol containing 2-6 carbon atoms. It discloses the use of a sweetening agent and a flavoring agent on page 50. The examples further disclose formation of the lactam degradation product is limited by the addition of the polyhydric alcohol.

Instant independent claims 1 and 14 differ over the reference in reciting a composition having a pH of about 5.5 to about 7.0. Claim 14 further recites amounts of the alcohol and limits the amount of lactam degradation product that forms in storage.

Instant independent claim 6 differs over the reference in reciting a method of preparing a composition in which the alcohol is added to water and then the GABA analog is added to the solution.

Instant independent claim 9 differs over the reference in reciting that the GABA analog and the polyhydric alcohol are mixed while in powder form and then the liquid is added to the powder.

Art Unit: 1614

Instant independent claim 10 differs over the reference in reciting the same procedure as claim 9 in which the GABA analog and the polyhydric alcohol are mixed while in powder form, but further mixes the polyhydric alcohol with a sweetener and a flavoring agent in water before adding the powder to the liquid.

Dependent claims recite pH, specific polyhydric alcohol and amounts, amount of lactam and intended use of the composition.

However, in the absence of a showing of unexpected results, no criticality is seen in the pH, amounts and type of polyhydric alcohol and order of mixing. That is because once the ingredients of a composition and a method of making it are known, it is within the skill of the artisan to determine these values. In re Eisenhut 114 USPQ 287, In re Aller 105 USPQ 233. Furthermore, intended use does not impart patentability to a composition claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/602,215

Page 5

Art Unit: 1614

The official fax number is 703-872-9806

Rebecca Cook

A handwritten signature in black ink, appearing to read 'Rebecca Cook', with a long, sweeping horizontal stroke extending to the right.

Primary Examiner

Art Unit 1614

September 9, 2004